

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/24/2011 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 7 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al. "Nelson"*.

Regarding Claims 1-2, 7 and 14-20, *Nelson* discloses a system and a method implemented by a computer program product comprising instructions for enabling a computer to: acquire ultrasound data with a transducer for at least a portion of a body organ (fetal heart) (Page 1, "Introduction"); generate and define at least one other plane with respect to a reference plane (e.g. "arbitrary") for the

body organ based on specific data including spatial positions within the organ that define a relationship of the at least one other plane to the reference plane (Pages 4-5, "Fetal Cardiac Data Visualization") and to display automatically and substantially simultaneously, at least two ultrasound images corresponding to at least of the reference plane and data defining the at least one other plane (Fig. 5). It should be noted that the generated planes are defined by a spatial mathematical relationship which relate the planes to one another by either a shift or rotation from the reference plane with respect to an organ (i.e. 90°). Examiner notes that Applicant has defined a reference plane (Specification-Paragraph [0082]) as a plane that can be readily obtained by 2D ultrasonography (e.g. four-chamber of the heart). Applicant also discloses in the same paragraph that any plane can be used as a reference plane. Furthermore, Merriam Webster defines "arbitrary" as "*depending on individual discretion (as of a judge) and not fixed by law*". Thus, Examiner contends that neither the claim nor the specification precludes a selected "standard" plane from being an "arbitrary" reference plane.

As for Claims 3-4, *Nelson* discloses a reference plane as the four-chamber view and wherein the at least one other plane comprises data defining a ductal arch view (Fig. 5).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 5-6 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al.* "*Nelson*" in view of U.S. Patent No. 7,244,233 to *Krantz et al.* "*Krantz*".

Regarding Claims 5-6 and 12, *Nelson* discloses a system with a computer program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for organs as described above. However, *Nelson* is silent with respect to the specific limitation of the organ being a fetal head. Further, *Nelson* is silent with respect acquiring ultrasound images for each of the sagittal, transverse, and coronal planes.

Krantz teaches from within the same field of endeavor with respect to ultrasound imaging of a fetus, a computerized method wherein the head of a fetus is imaged (Column 3, Line 62-Column 4, Line 5). Furthermore, *Krantz*

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teaches it is considered a well know expedient in the art to obtain ultrasound images of the sagittal, transverse and coronal planes which would include the biparietal diameter (Column 10, Lines 26-36).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program instructions as disclosed by *Nelson* to acquire and display ultrasound fetal head images acquired in the sagittal, transverse and coronal planes as described by *Krantz* in order to enhance and detect of fetal abnormalities using ultrasound.

With regard to Claim 13, Examiner contends the displaying disclosed by *Nelson* is displayed substantially in real time.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al.* "*Nelson*" in view of U.S. Patent No. 7,244,233 to *Krantz et al.* "*Krantz*" as applied to claim 5 above, and further in view of U.S. Patent No. 6,306,089 to *Coleman et al.* "*Coleman*".

Regarding Claim 6, *Nelson* in view of *Krantz* disclose a computer program product program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above.

However, *Nelson* in view of *Krantz* are silent with respect to the specific limitation of wherein the reference plane is of the biparietal diameter.

Coleman teaches from within a similar field of endeavor with respect to fetal imaging wherein it is considered a well known expedient in the art to obtain an image plane to effectively measure the biparietal diameter of a fetus (Column 5, Lines 6-35).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the reference plane for imaging of a fetal organ as disclosed by *Nelson* in view of *Krantz* to include a reference plane which includes the biparietal diameter of the fetal head as described by *Coleman* in order to visualize vital organs of a fetus. Examine notes that such a modification requires nothing more than the mere combination of known prior art techniques when imaging the fetal head to yield predictable results, which has previously been held as unpatentable (see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

8. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al.* "*Nelson*" in view of U.S. Patent No. 6,290,648 to *Kamiyama et al.* "*Kamiyama*" in further view of *Applicants Admission* of the prior art.

Regarding Claims 9-11, *Nelson* discloses a system with a computer program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above. *Nelson* is silent with respect to a computer program comprising image recognition software to

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facilitate the medical evaluation comprising steps to recognize a specific structure within an image, compare the structure with a reference image, and identify at least one of a normal and abnormal anatomical characteristic of the structure.

Kamiyama teaches an ultrasound diagnostic imaging apparatus (abstract) comprising image recognition software used to facilitate a medical evaluation (Column 7, Lines 58-67-Column 8, Lines 1-30). Furthermore, *Kamiyama* teaches wherein the software recognizes a specific structure within an image, compares the structure with a reference image, and identifies at least one of a normal and abnormal anatomical characteristic of the structure (Column 8, Lines 31-67).

Examiner further notes that Applicant has disclosed in the Specification, Paragraph [0067], "*One or more embodiments of the present invention can utilize, for example, standard (e.g. off-the-shelf) image recognition software to assess the level of the standardized planes and diagnose, or facilitate diagnosis...*". Examiner notes that an "off-the-shelf" program is considered to be well known and commercially available prior to the claimed invention. Therefore, one of ordinary skill in the art would readily recognize a modification to include well known computer software program as disclosed by Applicant and *Kamiyama* to evaluate acquired image data.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al.*

"*Nelson*" in view of NPL "Sonography of the Normal Fetal Heart: A Practical Approach" to *Frates*.

Regarding Claim 21, *Nelson* discloses a computer program product comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above. However, *Nelson* is silent with respect to obtaining image data corresponding to a number of gestational weeks. Examiner notes that it is considered a well known expedient in the art to correlate image acquisition of fetal organs with data such as gestational weeks as described by *Frates* (Fig. 11 A-D) since the fetus position changes during fetal development.

10. Claims 1, 7 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL "Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Council on Clinical Cardiology of the American Heart Association" to *Cerqueira et al.* "*Cerqueira*".

Regarding Claims 1, 7 and 14-17, *Clark* discloses a system and a computer program method comprising instructions for enabling a computer to: acquire ultrasound image data for at least a portion of a body organ (Column 1, Lines 37-50; Column 2, Lines 25-38). *Clark* further discloses obtaining a 3D

volume and displaying a plurality of views to a user which are automatically derived from the 3D data set (Column 3, Lines 35-47).

However, *Clark* is silent with respect to how the plurality of views are generated to define at least one other plane with respect to a reference plane for the body organ including spatial positions within the organ that define a relationship of the at least one other plane to the reference plane.

Cerqueira teaches an optimal approach for use in research and clinical patient management involving cardiac perfusion and function wherein at least one other plane is generated and defined with respect to a reference plane (e.g. "arbitrary") for the body organ which is based on specific data including spatial positions within the organ (Page 540 "Orientation of the Heart", "Recommendation", "Name for Cardiac Planes" and "Recommendation").

Examiner notes that by obtaining an "arbitrary reference plane" (i.e. "apical 4-chamber echocardiographic view"), *Cerqueira* also approximates the horizontal long-axis view (i.e. "standardized plane"). Furthermore, Applicant has defined a reference plane (Specification-Paragraph [0082]) as a plane that can be readily obtained by 2D ultrasonography (e.g. four-chamber of the heart) which is considered a "standard reference plane". Applicant also discloses in the same paragraph that any plane can be used as a reference plane. Moreover, Merriam Webster defines "arbitrary" as "*depending on individual discretion (as of a judge) and not fixed by law*". Thus, Examiner contends that neither the claim nor the

specification precludes a selected "standard" plane from being an "arbitrary" reference plane.

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program as disclosed by *Clark* to generate and define at least one other imaging plane with respect to a reference plane as described by *Cerqueira* in order to accurately define and display other planes with respect to the reference plane in an acquired 3D volume to visualize views which cannot be directly imaged by 2-D imaging systems. Such a modification requires nothing more than the mere combination of known prior art techniques to yield predictable results, which has previously been held as unpatentable (see for precedent *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

11. Claims 2-4 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL "Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Council on Clinical Cardiology of the American Heart Association" to *Cerqueira et al.* "*Cerqueira*" as applied to claim 1 above, and further in view of NPL "Fetal Heart Assessment Using Three-Dimensional Ultrasound" to *Nelson et al.* "*Nelson*".

Regarding Claim 2, *Clark* in view of *Cerqueira* disclose a computer program product comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for an organ (heart) as described above.

However, *Clark* in view of *Cerqueira* do not expressly disclose wherein the body organ is a fetal heart.

Nelson discloses a system and a method implemented by a computer program product comprising instructions for enabling a computer to: acquire ultrasound data with a transducer for at least a portion of a body organ (fetal heart) (Page 1, "Introduction).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program as described by *Clark* in view of *Cerqueira* to be used to perform it on a fetal heart as described by *Nelson* in order to accurately visualize a vital organ of a fetus.

As for Claims 3-4, *Nelson* discloses a reference plane as the four-chamber view and wherein the at least one other plane comprises data defining a ductal arch view (Fig. 5)

As for Claims 18-20, *Nelson* also discloses generating and defining at least one other plane with respect to a reference plane for the body organ based on specific data including spatial positions within the organ that define a relationship of the at least one other plane to the reference plane (Pages 4-5, "Fetal Cardiac Data Visualization") and to display automatically and substantially simultaneously, at least two ultrasound images corresponding to at least of the

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reference plane and data defining the at least one other plane (Fig. 5). It should be noted that the generated planes are defined by a spatial mathematical relationship which relate the planes to one another by either a shift or rotation from the reference plane with respect to an organ (i.e. 90°).

12. Claims 5-6 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL “Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Council on Clinical Cardiology of the American Heart Association” to *Cerqueira et al.* “*Cerqueira*” as applied to claim 1 above, and in further view of U.S. Patent No. 7,244,233 to *Krantz et al.* “*Krantz*”.

Regarding Claims 5-6 and 12, *Clark* in view of *Cerqueira* discloses a system with a computer program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for organs as described above. However, *Clark* in view of *Cerqueira* is silent with respect to the specific limitation of the organ being a fetal head. Further, *Clark* in view of *Cerqueira* is silent with respect acquiring ultrasound images for each of the sagittal, transverse, and coronal planes.

Krantz teaches from within the same field of endeavor with respect to ultrasound imaging of a fetus, a computerized method wherein the head of a fetus is imaged (Column 3, Line 62-Column 4, Line 5). Furthermore, *Krantz*

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teaches it is considered a well know expedient in the art to obtain ultrasound images of the sagittal, transverse and coronal planes which would include the biparietal diameter (Column 10, Lines 26-36).

Therefore, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the computer program instructions as disclosed by *Clark* in view of *Cerqueira* to acquire and display ultrasound fetal head images acquired in the sagittal, transverse and coronal planes as described by *Krantz* in order to enhance and detect of fetal abnormalities using ultrasound.

With regard to Claim 13, *Clark* discloses wherein the display is “real-time” (Column 2, Lines 21-23).

13. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL “Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Council on Clinical Cardiology of the American Heart Association” to *Cerqueira et al.* “*Cerqueira*” as applied to claim 1 above, and in view of in view of U.S. Patent No. 6,290,648 to *Kamiyama et al.* “*Kamiyama*” in further view of *Applicants Admission* of the prior art.

Regarding Claims 9-11, *Clark* in view of *Cerqueira* discloses a system with a computer program comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above. *Clark* in

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view of *Cerqueira* is silent with respect to a computer program comprising image recognition software to facilitate the medical evaluation comprising steps to recognize a specific structure within an image, compare the structure with a reference image, and identify at least one of a normal and abnormal anatomical characteristic of the structure.

Kamiyama teaches an ultrasound diagnostic imaging apparatus (abstract) comprising image recognition software used to facilitate a medical evaluation (Column 7, Lines 58-67-Column 8, Lines 1-30). Furthermore, *Kamiyama* teaches wherein the software recognizes a specific structure within an image, compares the structure with a reference image, and identifies at least one of a normal and abnormal anatomical characteristic of the structure (Column 8, Lines 31-67).

Examiner further notes that Applicant has disclosed in the Specification, Paragraph [0067], "*One or more embodiments of the present invention can utilize, for example, standard (e.g. off-the-shelf) image recognition software to assess the level of the standardized planes and diagnose, or facilitate diagnosis...*". Examiner notes that an "off-the-shelf" program is considered to be well known and commercially available prior to the claimed invention. Therefore, one of ordinary skill in the art would readily recognize a modification to include well known computer software program as disclosed by Applicant and *Kamiyama* to evaluate acquired image data.

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14. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,174,285 to *Clark* in view of NPL "Standardized Myocardial Segmentation and Nomenclature for Tomographic Imaging of the Heart: A Statement for Healthcare Professionals from the Cardiac Imaging Committee of the Council on Clinical Cardiology of the American Heart Association" to *Cerqueira et al.* "*Cerqueira*" as applied to claim 1 above, and in view of in view of NPL "Sonography of the Normal Fetal Heart: A Practical Approach" to *Frates*.

Regarding Claim 21, *Clark* in view of *Cerqueira* discloses a computer program product comprising instructions for enabling a computer to acquire a plurality of ultrasound image planes for fetal organs as described above.

However, *Nelson* is silent with respect to obtaining image data corresponding to a number of gestational weeks. Examiner notes that it is considered a well known expedient in the art to correlate image acquisition of fetal organs with data such as gestational weeks as described by *Frates* (Fig. 11 A-D) since the fetus position changes during fetal development.

Response to Arguments

Applicant's arguments filed 02/01/2011 have been fully considered but they are not persuasive. In particular, Applicant has argued that the cited references fail to teach or suggest defining at least one other plane with respect to an "arbitrary" reference plane. It is undisputed that both *Nelson* and *Clark* suggest particular planes (e.g. standard locations-See Applicant's arguments Page 7, Paragraphs 2 and 3). As stated

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in the rejection above, Merriam Webster defines "arbitrary" as "*depending on individual discretion (as of a judge) and not fixed by law*". Examiner further notes that Applicant has defined a reference plane (Specification-Paragraph [0082]) as a plane that can be readily obtained by 2D ultrasonography (e.g. four-chamber of the heart) which is considered a "standard reference plane". Applicant also discloses in the same paragraph that any plane can be used as a reference plane. Thus, Examiner contends that neither the claim nor the specification precludes a selected "standard" plane from being an "arbitrary" reference plane.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER COOK whose telephone number is (571)270-7373. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. C./
Examiner, Art Unit 3737

/BRIAN CASLER/
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